PROTOCOL FOR AN EVALUATION OF AN ISOPROPYL ALCOHOL HANDRUB AND A CHG SCRUB FOR ANTIMICROBIAL EFFECTIVENESS AND SUBSTANTIVITY IN THE SURGICAL SCRUB USING NORMAL SKIN FLORA

FOR: STERIS® Corporation

HTR Study No.: 03-121432-106
STERIS® Ref.: 02-0002.00

ADDENDUM

The identity of the 63% by volume isopropyl alcohol product has been blocked out in this protocol.

TABLE OF CONTENTS

Exhibits:

1.0 INTRODUCTION

This study is to evaluate the efficacy of [redacted] a 63% by volume isopropyl alcohol hand rub in a Surgical Scrub Test. This study is based on the procedures described in the Tentative Final Monograph (Vol. 59, No. 116, June 17, 1994, FR 31402).

2.0 OBJECTIVE

To determine the antibacterial effectiveness of the test product when used in a surgical scrub procedure as shown by a reduction in resident bacteria. At least a 1 $\log_{10}$ reduction on each hand will be achieved within 1 minute of product use on the first day, a 2 $\log_{10}$ reduction of the microbial flora on each hand within 1 minute of the first product use on the second day and a 3 $\log_{10}$ reduction of the microbial flora on each hand within 1 minute of product use on the fifth day when compared to the established baseline. Regrowth will be measured to determine whether the bacterial cell count on each hand does not exceed baseline within 6 hours of product use on the first, second and fifth test days.

3.0 STUDY SPONSOR AND MONITOR

STERIS Corporation
Product Development, St. Louis Operations
PO Box 147
St. Louis, MO 63166-0647
Telephone: 314-290-4754
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Monitors: Jeanne Medvick MT (ASCP), MBA, CIC
Nancy Kaiser B.S.

4.0 INVESTIGATIVE ORGANIZATION AND PERSONNEL

Hill Top Research Inc. (HTR)
Main and Mill Streets
Miamiville, OH 45147
Telephone No.: 513-831-3114
Fax No.: 513-831-1217

Investigator: Gayle K. Mulberry, M.S.
Sub-Investigator: Ann R. Brady, B.A.G.S.
Medical Consultant: E. Linn Jones M.D., D.A.B.D.

5.0 CLINICAL RESEARCH STANDARDS

The protocol, informed consent, relevant supporting information and subject recruitment materials will be reviewed by an Institutional Review Board (IRB) in accordance with the regulations of the United States Food and Drug Administration (FDA) as described in Title 21 of the Code of Federal Regulations, Parts 50 and 56, applicable laws, and the IRB requirements. Written approval by the Board must be obtained prior to the recruitment of subjects and the initiation of the study.

Any changes to the protocol will be submitted to the IRB for review and approval before implementation. A protocol change intended to eliminate an apparent immediate hazard to subjects may be implemented immediately provided that the reviewing IRB is notified within 5 working days.

The Investigator will provide each subject with full and adequate verbal and written information using the IRB approved informed consent document, including the objective and procedures of the study and the possible risks involved before inclusion in the study. Informed consent must be obtained prior to performing any study-related procedures. A copy of the signed informed consent must be given to the study subject.

The study will be conducted in accordance with the Good Clinical Practice Regulations, the Standard Operating Procedures of Hill Top Research, Inc., the study protocol, and protocol amendment(s).

6.0 EXPERIMENTAL DESIGN

The study, which will follow at least a two-week washout period, will consist of a one-week baseline period in which subjects that exhibit counts greater than or equal to 1.5×10^5 on each hand after the first and second estimates of the baseline population will be assigned a place in the study. Subjects will apply the test product 11 times over a five-day period. Subjects' hands will be sampled within 1 minute after the first application of the test product and approximately 6 hours later on Day 1 of the study to determine bacterial reduction of the resident flora from baseline. On Day 2, subjects' hands will be sampled within 1 minute and approximately 6 hours after the first of three applications. On Day 5, subjects' hands will be sampled within 1 minute and approximately 6 hours after the one application of the test product. A marketed 4% CHG product will be used as a positive control.

7.0 TEST ARTICLES

7.1 Test Articles

Product Identification	Description
[redacted]	63% by volume isopropyl alcohol hand rub
Hibiclens	4% CHG w/v positive control

7.2 Apparatus, Materials, and Reagents

7.2.1 Colony Counter: Any of several types may be used.

7.2.2 Incubator: Any incubator capable of maintaining a temperature of 30 ± 2°C may be used.

7.2.3 Sterilizer: Any suitable steam sterilizer capable of producing the conditions of sterility is acceptable.

7.2.4 Timer: One that can be read for minutes and seconds.

7.2.5 Hand Washing Sink: A sink of sufficient size to permit subjects to wash without touching hands to sink surface or other subjects.

7.2.6 Water Faucet: To be located above the sink at a height which permits the hands to be held higher than the elbows.

7.2.7 Tap Water Temperature Regulator and Temperature Monitor: To monitor and regulate water temperature to 40 ± 2°C.

7.2.8 Sterile Syringes: Of appropriate size for dispensing test article(s).

7.2.9 Bacteriological Pipettes: Sterile pipettes of size suitable for dilution preparation and plating.

7.2.10 Water Dilution Bottles: Any sterilizable container having a 150-200 mL capacity and tight closures may be used.

7.2.11 Bland Soap: Johnson & Johnson's Baby Wash Head-to-Toe.

7.2.12 Gloves: Sterile loose fitting, powder free gloves of latex, unlined, containing no antimicrobial.

7.2.13 Sampling Solution: Dissolve 0.4 g KH_2PO_4, 10.1 g Na_2HPO_4 and 1.0 g Triton X-100 in one liter distilled water. Adjust to pH 7.8 ± 0.1. Dispense an appropriate volume into water dilution bottles, or other suitable containers to achieve a final volume of 75 ± 1 mL after autoclaving at 121°C.

7.2.14 Sampling Solution: Dissolve 0.4 g KH_2PO_4, 10.1 g Na_2HPO_4 and 1.0 g Triton X-100 in one liter distilled water and containing an antimicrobial inactivator* specific for the test formulation. Adjust to pH 7.8 ± 0.1. Dispense an appropriate volume into water dilution bottles, or other suitable containers to achieve a final volume of 75 ± 1 mL after autoclaving at 121°C.

7.2.15 Dilution Fluid: Butterfield's phosphate buffered water adjusted to pH of 7.2 and containing an antimicrobial inactivator specific for the test formulation.

7.0 TEST ARTICLES (CONT.)

7.2.16 Plating Medium: Trypticase Soy Agar with neutralizers. Selection of plating media will be directed by the neutralization assay results.

7.2.17 Kit Product for Washout Period: non-antimicrobial deodorant/antiperspirant, bar soap, and shampoo, disposable polyvinyl gloves.

***Note 1:** Prior to initiation of this study, the adequacy of the antimicrobial product neutralizers will be confirmed in accordance with Standard Test Methods for Evaluation of Inactivators of Antimicrobial Agents (ASTM E 1054-02).

8.0 SUBJECT SELECTION

8.1 Number of Subjects

Test N= 24, Neutralization N=6

Approximately forty (40) volunteers will be recruited to assure 24 evaluable subjects in the test phase of this study. Approximately ten (10) additional volunteers will be recruited to enroll six (6) subjects in the neutralization assay phase of the study. A written and dated consent form will be obtained from each subject and filed by the investigator with the subject's records in accordance with 21 CFR 50 & 56.

8.2 Criteria for Inclusion

8.2.1 Males and/or females, no less than 18 years of age.

8.2.2 Healthy individuals of any race, free of chronic or allergic skin disorders.

8.2.3 Subjects are cooperative and willing to answer a questionnaire (see Exhibit A) and sign and date a written informed consent statement (see Exhibit B).

8.2.4 Hands of all subjects are free from cuts and abrasions.

8.2.5 Subjects are willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and hand washing during the entire study.

8.2.6 Subjects of child bearing potential that are willing to use an acceptable means of birth control, other than oral contraceptives, such as (a condom with spermicide, IUD, diaphragm and contraceptive cream or foam).

8.2.7 Subjects are willing to comply with all study protocol requirements.

8.2.8 Subjects are willing to remove all rings, watches, and other jewelry from hands and wrists.

8.0 SUBJECT SELECTION (CONT.)

8.3 Exclusions

The following exclusions apply during the pretest, baseline, and treatment period.

8.3.1 Exposure to topical or systemic antimicrobials. This restriction includes, but is not limited to, antibiotics, antimicrobial antiperspirants, deodorants, shampoos, lotions, soaps, body powders, and materials such as solvents, acids, or alkali.

8.3.2 Bathing in chlorinated pools and hot tubs.

8.3.3 Any form of dermatitis, open wounds, or other skin disorders (particularly on the hands) that may affect the integrity of the study.

8.3.4 Anyone not willing to comply with the requirements of the protocol.

8.3.5 Are pregnant, lactating or using oral contraceptives two weeks before the start of the study period and during the entire study period.

8.3.6 Have been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, or AIDS (or HIV positive); and/or

8.3.7 Have any other condition, medical or otherwise, which in the opinion of the Investigator would preclude participation.

8.3.8 Any person with artificial nails, nail polish, or their fingernails longer than 1mm free edge.

8.3.9 Any person with a known sensitivity or allergy to alcohol and/or chlorhexidine gluconate (CHG).

8.3.10 Any person who is known to be sensitive to latex products.

8.3.11 Exclude from the treatment phase of the study any subject with a first or second baseline count $<1.5 \times 10^5$ CFU per hand.

9.0 SUBJECT WITHDRAWAL

After admission to the study, the subject may withdraw at any time for any reason and possible such reason will be recorded fairly and accurately.

10.0 PROCEDURES

This study will be divided into four phases as follows: pre-test, baseline testing, practice product application and treatment.

10.1 Pre-test Phase

10.1.1 The first two weeks of the study are designed as a period to prepare the subjects by eliminating topical substances which may interfere with the study. Subjects are recruited and given instructions, both verbal and written, about the procedures to be followed during their participation in the study. Subjects are to refrain from the use of soaps, shampoos, etc. which contain antibacterial agents.

10.1.2 Subjects are given a kit containing a non-antimicrobial soap, shampoo, and deodorant/antiperspirant for use during the entire study period. A copy of the instructions provided to the subject is attached as Exhibit C.

10.1.3 Twenty-four (24) subjects in the test phase will be randomly assigned to one of three groups. Randomization will occur by two arms of the test article and one positive control. Additional subjects will be randomized to one of the two products in the neutralization assay phase. The randomization scheme utilized will be included in the final report.

10.2 Baseline Determination Phase

10.2.1 After refraining from using topical and systemic antimicrobials for at least two weeks, volunteers perform a wash with the baseline control soap. After washing, determine first estimate of baseline bacterial population by sampling hands and enumerating the bacteria in the sampling solution. This is Day 1 of "Baseline Period". Repeat this baseline determination procedure on Days 5 and 7 of "Baseline Period" to obtain three estimates of baseline populations. Subjects are not to have washed their hands for at least two hours prior to a baseline determination.

10.2.2 After obtaining the first and second estimates of the baseline populations, select, as subjects, at least 24 subjects who exhibited at each of the first two sampling intervals counts $\geq 1.5 \times 10^5$ for each hand. The three estimates of the baseline population, obtained for each of the 24 selected subjects, are averaged to obtain the mean baseline counts for calculating reductions.

10.2.3 The Investigator will divide the selected subjects into three groups.

10.0 PROCEDURES (CONT.)

10.2.4 One group will consist of 9 subjects who will dispense 5 mL of [redacted] to the palm of one hand and spread over both hands and lower two-thirds of the forearms until dry. They will dispense [redacted] a second time in a 2.5 ml allocation to the palm of one hand and spread evenly over both hands and wrists until dry or up to 120 seconds. This will be Arm A.

10.2.5 Another group of 9 subjects will apply [redacted] as described in section 10.2.4 with the addition of a third application of a 2.5 mL allocation of product and spread over both hands and wrists until dry or up to 120 seconds. This will be Arm B.

10.2.6 The third group will consist of 6 subjects who will apply the positive control product, Hibiclens, in two applications. Five (5) mL of Hibiclens will be dispensed into the wet hands of the subjects and the subjects will scrub for 3 minutes with a wet brush and then rinse thoroughly. The subjects will repeat the procedure. This will be Arm C.

10.2.7 Each of the groups are further subdivided and randomly assigned to sampling groups. Equal numbers of subjects are assigned for sampling time and handedness.

A typical balanced randomization plan for testing a block of 6 subjects follows:

	Post Treatment Sampling Time	
Subject Number	**Immediate (within 1 minute)**	**6 Hour ± 15 minutes**
1	Left Hand	Right Hand
2	Left Hand	Right Hand
3	Right Hand	Left Hand
4	Right Hand	Left Hand
5	Left Hand	Right Hand
6	Right Hand	Left Hand

On Day 1 of the test period, no sooner than twelve hours nor longer than four days after completion of their last baseline determination, subjects perform initial treatment with the assigned test article. According to the sampling plan, the bacterial populations on one hand of four subjects are determined at the immediate time (within 1 minute) after treatment with test article. The bacterial populations on the six subjects' other hand and the hands of the remaining subjects is determined according to the random sampling plan. The bacterial

10.0 PROCEDURES (CONT.)

population is determined by sampling hands and enumerating the bacteria in the sampling solution as specified in 10.5 and 10.6.

On Day 2 of the test period, the sampling procedure is repeated following the first treatment of that day; two additional treatments are performed on this day. On Days 3 and 4, three treatments are performed with the assigned test article with at least a one-hour interval between treatments. On Day 5, on additional treatment is performed followed by bacterial sampling as described for Day 1 and 2. In summary, subjects are to be treated a total of eleven times with the test articles, once on Day 1 and Day 5 and three times per day on Days 2, 3 and 4.

10.3 Washing Technique for Baseline Determinations

10.3.1 Subjects will clip fingernails to <1.0 mm free edge. Remove all jewelry from hands and arms.

10.3.2 Wet hands including two-thirds of forearm under running tap water (40 ± 2°C) for 30 seconds. Clean under fingernails with a nail pick. Rinse nails.

10.3.3 Wash hands and forearms with 5 mL of baseline control soap dispensed from a syringe for 30 seconds using water as required to develop lather. Maintain hands higher than elbows during this procedure.

10.3.4 Rinse hands and forearms thoroughly removing all lather for 30 seconds under tap water.

10.3.5 The hands of the subjects are placed into sterile latex gloves and 75 mL of sampling solution is instilled into each glove. The gloves are secured at the wrist and the hands are aseptically massaged for one minute, paying particular attention to the fingernails.

10.3.6 Aliquots of the sampling solution (1.0 mL aliquot) are removed from the gloves within 1 minute of completing the massage and immediately placed into dilution tubes containing dilution fluid with neutralizer.

10.4 Treatment Phase

10.4.1 Procedure using [redacted] Arm A

10.4.1.1 Subjects' fingernails are checked to determine if they are <1.0 mm free edge. All jewelry is removed from the hands and arms.

10.4.1.2 Wet hands and fingernails under running tap water (40 ± 2°C). Clean under nails with pick. Rinse fingernails and hands. Dry thoroughly with a paper towel.

10.0 PROCEDURES (CONT.)

10.4.1.3 Five (5) mL of [redacted] is dispensed in the palm of one hand. It is spread on both hands and forearms and rubbed into the skin until dry or up to 120 seconds. Particular attention is to be paid to the nails, cuticles, and the area between the fingers. No water or toweling is to be used on the hands during this process.

10.4.1.4 Two and a half (2.5) mL of [redacted] is dispensed into the palm of one hand, spread over both hands to wrists, and rubbed into the skin until dry or up to 120 seconds. No water or toweling is to be used during this process.

10.4.1.5 After the product has been rubbed into the skin, the hands of the subjects are placed into sterile latex gloves and 75 mL of sampling solution is instilled into each glove. The gloves are secured at the wrist and the hands are aseptically massaged for one minute, paying particular attention to the fingernails.

10.4.1.6 An aliquot of the sampling solution (5 mL) is removed from the gloves within 1 minute of completing the massage and immediately placed into dilution tubes containing dilution fluid with neutralizer.

10.4.2 Procedure Using [redacted], Arm B

10.4.2.1 Subjects' fingernails are checked to determine if they are <1.0 mm free edge. All jewelry is removed from the hands and arms.

10.4.2.2 Wet hands and fingernails under running tap water (40 ± 2°C). Clean under nails with pick. Rinse fingernails and hands. Dry thoroughly with a paper towel.

10.4.2.3 Five (5) mL of [redacted] is dispensed in the palm of one hand. It is spread on both hands and forearms and rubbed into the skin until dry or up to 120 seconds. Particular attention is to be paid to the nails cuticles, and the area between the fingers. No water or toweling is to be used on the hands during this process.

10.4.2.4 Two and a half (2.5) mL of [redacted] is dispensed into the palm of one hand, spread over both hands to wrists, and rubbed into the skin until dry or up to 120 seconds. No water or toweling is to be used with this product.

10.4.2.5 Two and a half (2.5) mL of [redacted] is dispensed into the palm of one hand, spread over both hands to wrists, and rubbed into the skin until dry or up to 120 seconds. No water or toweling is to be used with this product.

10.0 PROCEDURES (CONT.)

10.4.2.6 After the product has been rubbed into the skin, the hands of the subjects are placed into sterile latex gloves and 75 mL of sampling solution is instilled into each glove. The gloves are secured at the wrist and the hands are aseptically massaged for one minute, paying particular attention to the fingernails.

10.4.2.7 Sampling of hands will be done in accordance with 10.4.1.6.

10.4.3 Procedure using Hibiclens, Arm C

10.4.3.1 Subjects' fingernails are checked to determine if they are <1.0 mm free edge. All jewelry is removed from the hands and arms.

10.4.3.2 Subjects' wet their hands including two-thirds of forearms under running tap water (40 ± 2°C) for 30 seconds. Clean under the fingernails with a nail pick. Rinse fingernails and hands.

10.4.3.3 Pick up scrub brush with finger tips and place in sterile Petri dish.

10.4.3.4 Set and start timer for 3 minutes – time required for steps 10.4.3.6 and 10.4.3.7.

10.4.3.5 Five (5.0) mL of the Hibiclens is dispensed into subjects' cupped hands from a syringe. Subjects immediately distribute the material over hands and lower two-thirds of forearms.

10.4.3.6 Subjects pick up scrub brush and alternately scrub right hand and lower two-thirds of forearm and left hand and lower two-thirds of forearm.

The timing of the first scrub sequence, as it relates to the use of the brush, is shown below:

Area scrubbed	Brush part used	Time
Fingernails, Cuticle	Bristles	30 seconds
Interdigital spaces	Bristles	30 seconds
Palm of hand	Sponge	10 seconds
Back of hand	Sponge	10 seconds
Forearm	Sponge	10 seconds

Place brush in sterile dish within easy reach. Rinse both hands and the lower two-thirds of the forearms for 30 seconds.

10.0 PROCEDURES (CONT.)

10.4.3.7 Repeat steps 10.4.3.5 through 10.4.3.6 so that each hand and forearm is scrubbed twice. The second scrub and rinse should be limited to the lower one-third of the forearms and the hands. The timing of the second scrub sequence, as it relates to the use of the brush, is shown below:

Area scrubbed	Brush part used	Time
Fingernails, Cuticle	Bristles	30 seconds
Interdigital spaces	Bristles	30 seconds
Palm of hand	Sponge	10 seconds
Back of hand	Sponge	10 seconds
Forearm	Sponge	10 seconds

10.4.3.8 Perform final rinse. Rinse each hand and forearm separately for one minute per hand.

10.4.3.9 Sampling of hands will be done in accordance with 10.4.1.6.

10.5 Sampling Techniques

10.5.1 At specified sampling times, aseptically add 75 mL of sampling solution to gloved hand to be sampled and occlude glove above wrist. (Note: An antimicrobial inactivator specific for the test articles being evaluated is included in the sampling solution used to collect the bacterial samples from the hands following the final treatment with the test articles. No inactivator will be included in the sampling solution used for baseline bacterial collections or for samplings prior to the final treatment.)

10.5.2 After adding sampling solution, a technician will uniformly massage all surfaces of gloved hand for one minute, paying particular attention to the area under the nails.

10.5.3 After massaging, aseptically remove a 5 mL aliquot from the 75 mL of sampling solution in the glove using a pipet and immediately transfer to a 45 ml volume of dilution fluid containing a suitable antimicrobial inactivator.

10.0 PROCEDURES (CONT.)

10.6 Enumeration of Bacteria in Sampling Solution

Enumerate the bacteria in the sampling solution by a standard plate count procedure described in Standard Method for the Evaluation of Dairy Products, (15th Ed.) using soybean-casein digest agar and a suitable neutralizer (inactivator) for the antimicrobial where necessary. Plate in duplicate. Incubate plated sample at 30 ± 2°C for 48 ± 4 hours before reading. Use dilution fluid as described in 7.2.15 with suitable inactivator for preparing sample dilutions. Record baseline bacterial counts on Exhibit D and test bacterial counts on Exhibit E.

11.0 EVALUATION

The raw microbial counts will be recorded on data collection forms for each subject. The number of viable bacteria recovered from each hand will be calculated by multiplying the dilution factor by the mean plate count. Bacterial counts will be transformed into $\log_{10}$ counts.

12.0 ADVERSE EXPERIENCES

12.1 Definitions

An Adverse Event/Experience is any unexpected or undesirable experience occurring to a subject during a study, which may or may not be related to the test article. All adverse event/experiences will be recorded (Exhibit F) and reported according to the Standard Operating Procedures of STERIS Corporation CS-212-00.

A Serious Adverse Drug Event/experience is any adverse drug experience occurring at any dose that results in any of the following outcomes:

Death;
A life-threatening adverse drug experience;
In-patient hospitalization or prolongation of existing hospitalization;
A persistent or significant disability/incapacity;
A congenital anomaly/birth defect.

12.0 ADVERSE EXPERIENCES (CONT.)

Important medical event/experiences that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

An Unexpected Adverse Drug Event/Experience is any adverse drug event/experience not listed in the current labeling for the test article or the current investigator's brochure. Where test article labeling or investigator's brochure is not available, anticipated experience will be listed in the protocol based on the pharmacological property of the test article.

12.2 Follow-up

If an adverse event/experience occurs, the subject, under the direction of the Investigator (or designee), may be referred to the Hill Top Research, Inc. consultant physician for treatment.

Serious or Unexpected Drug Event/Experience will be followed to resolution to the extent possible (e.g. medical attention by the subject's primary care physician).

12.3 Notification

The sponsor will be notified of all adverse event/experiences. Any Serious or Unexpected Adverse Drug event/Experience which occurs during the study must be reported promptly by the investigator to the sponsor and the reviewing IRB, where applicable, within 24 hours of the information being reported to Hill Top Research, Inc.

13.0 DATA ANALYSIS

Raw data from the three baseline determinations will be converted to $\log_{10}$ values and then averaged to determine the baseline count. Log reductions will be calculated by subtracting the post-treatment log count from the average of the three baselines.

The paired difference in log reductions between the test article and baseline values will be calculated for each subject at each time period for each product. Statistical significance will be analyzed using a paired-samples t-test with 2-sided alpha =0.05.

12.0 ADVERSE EXPERIENCES (CONT.)

An analysis of variance will also be conducted to determine if there is significant difference in efficacy between the standard product application method and each modification.

14.0 REPORT

The final report will summarize the method, any and all deviations that occurred during the course of the study, data and conclusions relative to the test materials and the subjects. Source data will be retained by the testing facility. The original source data will be maintained according to the investigator's standard operating procedure. A copy of the source documents may be obtained upon request of the Study Sponsor. Copies of transcribed data will be incorporated in the report.

15.0 NOTICE

No amendment to the protocol will be permitted without approval from the Study Sponsor, Investigator, and the Institutional Review Board. Such changes will be documented in writing. Approval by the Board must be obtained prior to initiation of the amendment.

16.0 PROTOCOL APPROVAL

Submitted for Hill Top Research, Inc.

By: _____ _____
Gayle Mulberry, M.S. Date
Investigator

Accepted for: **STERIS® Corporation**

By: D. K _____ 7/15/03
Daniel Klein Date
Manager, Microbiology

_____ 7/15/03
Michael Ebers, M.A. Date
Manager, Regulatory Affairs

EXHIBIT A
MEDICAL QUESTIONNAIRE

HTR Study No.: 02-121276-1
Page: _____

Subject Initials _____/_____/_____ Date _____

Height _____ Weight _____ Occupation _____ Race _____

Age: _____ Sex: Male _____ Female _____ General Health: Good _____ Fair _____ Poor

1. Have you been medically diagnosed by a doctor as having any of the following medical conditions: diabetes, hepatitis, an auto-immune disease (Lupus erythematous, thyroiditis, etc.), an organ replacement, or an immunologic condition (AIDS, HIV positive, etc)?
   No ___ Yes ___ If yes, please explain: _____
2. Are you currently using or have you used any topical or systemic antimicrobial or any antibiotic medication (penicillin, tetracycline, erythromycin, antibiotic cream, etc.), for any reason, during the past 2 weeks?
   No ___ Yes ___ Which medications?_____
3. Are you currently using or have you used any of the following in the past two weeks? (cortisone, antibacterial/medicated soap, or dandruff/medicated shampoo) No ___ Yes ___
   Which product? _____
4. Are you sensitive to perfumes, fragrances or latex products? No ___ Yes ___ If yes, please describe:
   _____
5. Have your hands or forearms been exposed to strong detergents, solvents or other irritants during the last two weeks? No ___ Yes ___ If yes, please describe:_____
6. Are subjects finger nails greater than 1.0 mm free edge? No____ Yes ____ Is subject wearing artificial nails?
   No _____ Yes ____
7. Have you been swimming in a chlorinated pool or bathed in a hot tub in the past two weeks?
   No ___ Yes ___
   If subjects answer yes to any of the questions 1-7, please exclude from the test phase.

8. For Women Only: Are you pregnant or nursing? No ___ Yes ____
9. For Women Only: Have you taken birth control pills in the past two weeks? No ___ Yes ___
10. For Women Only: Are you of child bearing potential? No ___ Yes ____
11. For Women Only: Are you using an adequate means of birth control? No ___ Yes ____
    If subjects answer yes to question 8 or 9 or no to question 11(if the response to question 10 is yes), please exclude from the test phase.

12. Do you have any allergies to medicated soaps or skin antiseptics? No ___ Yes ____
    If yes, please explain: _____
    If subjects response indicates sensitivity to any antimicrobial product, exclude from the test phase.

13. Are you currently using any prescription or non-prescription medication?
    No ___ Yes ___ Which medication? _____
14. Are you presently seeing or being treated by a doctor for allergies, a skin problem, or any other medical condition?
    No ___ Yes ___ If yes, please describe: _____
15. Have you ever had:

	No	Yes	At present
Psoriasis	___	___	___
Eczema	___	___	___
Other skin problems	___	___	___
Skin Cancer	___	___	___
Allergy to chlorhexidine	___	___	___

If subjects answer yes and at present to any of the items in question 15, please exclude from the test phase.

INTERVIEWER'S USE ONLY

The skin on subject's hands and forearms was found to be free of any dermatoses, cuts, lesions, or other skin disorders. The subject considers himself/herself to be in good health as evidenced by answers to screening questions above.

Accepted _____ Consent Form _____ Excused _____ Reason: _____
Initial _____ Date _____ Subject Screen No. _____ Subject No. _____

INSTITUTIONAL REVIEW BOARD

OF

HILL TOP RESEARCH, INC.

Nancy J. Pelc, M.D., Chairman

PROJ. NO. 03-121432-1
PAGE NO. T-1

July 16, 2003

Gayle K. Mulberry, M.S.
Hill Top Research, Inc.
Main and Mill Streets
Miamiville, OH 45147

Ref:	HTR No. 03-121432-106 Sponsor Study No.: 02-0002.00
Title:	AN EVALUATION OF [redacted]AND A CHG SCRUB FOR ANTIMICROBIAL EFFECTIVENESS AND SUBSTANTIVITY IN THE SURGICAL SCRUB USING NORMAL SKIN FLORA
Protocol Date:	July 14, 2003
Sponsor:	STERIS® Corporation

Dear Mr. Mulberry:

The Institutional Review Board of Hill Top Research, Inc. has reviewed and approved the above referenced study by the expedited review procedure. Documents included in this review were: protocol, consent forms (2), subject instructions and safety information. Approval of this study has been granted for one year from the date of this letter.

Please remember that the FDA requires you to receive approval from the IRB for any amendments or changes in the protocol or consent form and for any new advertisements. Serious and unexpected adverse experiences and unanticipated problems involving risk to subjects must be reported promptly to the IRB. If the study is expected to last beyond the one-year approval, you must request re-approval for continuation at least 30 days in advance of the expiration date.

The Institutional Review Board of Hill Top Research, Inc. is a duly constituted institutional review board under CFR, Title 21, Parts 50 and 56.

Sincerely,

Nancy J Pelc MD 7-16-03

Nancy J. Pelc, M.D. Date
Chairman

NJP/eb

Study Title: "Protocol for an Evaluation of [redacted] and a CHG Scrub for Antimicrobial Effectiveness and Substantivity in the Surgical Scrub Using Normal Skin Flora"

CONSENT FORM

INTRODUCTION: You are being asked to take part in a research study. Before you give your consent to be a subject, it is important that you take enough time to read and understand what your participation would involve. In preparing this consent form, it has been necessary to use some technical language. Please ask questions if there is anything you do not understand.

You will be given a signed copy of this consent form and any other necessary written information prior to the start of the study.

PURPOSE: The purpose of this research study is to determine the ability of two surgical handwash products to reduce the number of bacteria on the hands after use and to evaluate bacterial regrowth on the hands up to six hours after use. Approximately forty (40) people at least 18 years of age will be screened as potential subjects in this study. Twenty-four (24) subjects are expected to complete the 9-visit study.

TEST ARTICLES: You will be randomly assigned one of the two marketed surgical handwash products.

STUDY PROCEDURES: You must read and complete this consent form. You will then be given a kit containing a non-medicated bar soap, non-medicated shampoo, Ban® Deodorant/Antiperspirant and gloves to be used at least two weeks prior to the start of the actual study. You will be given written instructions on how to use the kit.

After at least two weeks, you will be required to return to the lab to enter the baseline period, which lasts seven days. You will be asked to complete a brief medical history questionnaire. It is possible that you may not be able to participate based on your answers to these questions or the condition of your skin. On Day 1, if you still qualify, you will wash your hands one time with a non-antibacterial soap. Loose-fitting latex gloves will be placed on both hands and the hands will be sampled. The sampling procedure involves adding a mild soap-like solution to each glove. A laboratory technician will then massage each hand for one minute. Afterwards, the gloves will be removed from the hands and the solution from each glove will be tested to determine the number of bacteria removed. You will return to the lab again on Days 5 and 7 to repeat this baseline sampling. If you qualify, the following week you will return to the lab to enter Day 1 of the Test Period. On this day, you will treat your hands and forearms with one of the two test materials. Your hands will be gloved. One hand will be sampled as above immediately after treatment and the other

hand after six hours of glove wear. Both hands will not be sampled at the same time. You will return to the lab on Day 2 to perform three additional treatments. Following the first treatment on Day 2, one hand will be sampled immediately and one hand after 6 hours of glove wear. After the final hand is sampled, the second and third treatments will be performed at least 1 hour apart. On Days 3 and 4 you will again return to the lab to perform three treatments each day, at least 1 hour apart. On Day 5 only one treatment is performed at the lab as on Day 1. One hand is again sampled immediately and one hand after 6 hours of glove wear.

FEMALES OF CHILDBEARING POTENTIAL: You may not participate in this study if you are pregnant or nursing. As part of giving your consent you must agree to have a urine pregnancy test at the start of the study. You must also agree to use an adequate means of birth control (a condom with spermicide, IUD, diaphragm and contraceptive cream or foam).

RISKS: Your hands and forearms may show a reaction. A reaction could be redness, swelling, itching, cracking, peeling, or in rare cases, blistering. No risks to you as a study participant, other than those described above as "reactions," are anticipated during the study. Reactions are usually due to irritation, although an allergic reaction might occur. If you become allergic, it is possible that future exposures to the same ingredient may cause a skin reaction. If this occurs, you will be provided with information to minimize the chance for future exposures.

You may experience risks or side effects that are not known at this time. You will be informed in a timely manner if new information becomes available that may influence your willingness to continue in this study.

BENEFITS: You will not benefit from the applications of test products but the study results may allow a new or improved product to be marketed.

ALTERNATIVE PROCEDURES/TREATMENTS: Because you are not being treated for a medical condition, alternative treatments do not apply to this study.

CONFIDENTIALITY: Information concerning you that is obtained in connection with this study will be kept confidential by Hill Top Research, except that the sponsoring company whose product is being tested will receive a copy of the study records. The records will be coded to protect your identity. In addition, the sponsoring company, the Institutional Review Board (IRB) and government regulatory agencies, including the U.S. Food and Drug Administration (FDA), may inspect the records of the study. Information obtained in the study may be used for medical or scientific publication, but your identity will remain confidential.

MEDICAL TREATMENT: If in the course of this study you experience illness, discomfort or injury that appears to be a result of the study, Hill Top Research will provide you with medical care at no cost to you. Providing such medical care is not an admission of legal responsibility. If such illness, discomfort or injury does occur, ask any staff member to arrange a meeting for you with the appropriate personnel.

In certain cases of illness or injury resulting from this study, workers' compensation coverage may be available. In accordance with Ohio law, Hill Top Research has secured workers' compensation coverage for participants in its studies and tests, and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

WHO TO CONTACT: If you have any questions about this study or in case of an emergency, contact Glenna, Study Coordinator at 513-831-3114, [redacted] during business hours (M-F, 8:00 A.M. - 5:00 P.M.) or Ann Brady, Study Manager at [redacted] after hours. In addition, if you have any questions as to your rights as a research subject, contact the Institutional Review Board of Hill Top Research, Nancy J. Pelc, M.D., Chairman, at [redacted].

IRB of
Hill Top Research
JUL 16 2003
Approved

VOLUNTARY PARTICIPATION/WITHDRAWAL: Your participation in this research study is strictly voluntary. You may refuse to participate or may discontinue participation at any time during the study without penalty or loss of benefits to which you are otherwise entitled.

If you agree to participate in this study, you are also agreeing to provide Hill Top Research with accurate information and to follow study instructions as given to you. If you fail to follow study instructions, your participation may be ended.

Your participation in the study may be discontinued at any time without your consent by the Investigator, the IRB, the FDA, or the sponsoring company.

COMPENSATION: You will be paid [redacted] for the completion of this study. You will be compensated according to the following schedule:

If you complete	Visit 1	you will receive	$0*
If you do not qualify	Visit 2	you will receive	[redacted]
If you complete	Visit 2	you will receive	[redacted]
If you complete	Visit 3	you will receive	[redacted]
If you complete	Visit 4	you will receive	[redacted]
If you complete or are an alternate	Visit 5	you will receive	[redacted]
If you complete	Visit 6	you will receive	[redacted]
If you complete	Visit 7	you will receive	[redacted]
If you complete	Visit 8	you will receive	[redacted]
If you complete	Visit 9	you will receive	[redacted]

*No payment-kit products given.
Payments will be made at the end of the study.

There are no anticipated expenses to you for participating in this study. All test related materials will be provided at no cost to you. (Bar soap, shampoo, antisperspirant/deodorant, and gloves)

IRB of
Hill Top Research
JUL 16 2003
Approved

CONSENT TO PARTICIPATE

I know that my participation in this study is voluntary and that I have the right to refuse to participate. I know that I may withdraw from the study at any time without penalty or loss of benefits to which I am otherwise entitled. If I withdraw or am dismissed for failure to obey rules or follow directions, I understand I will only be paid for the portion of the study that I have completed. If, in the judgment of the Investigator, it is best to discontinue my participation in the study for other reasons, I will be paid either in full or for that portion of the study already completed.

If I am a female of childbearing potential, I am not currently pregnant or nursing an infant. I am using an adequate means of birth control and, if I become pregnant or believe I have become pregnant, I will notify the Investigator immediately.

CONSENT: I have read all of the pages of this consent form and have been given an opportunity to ask questions about this study. Answers to such questions (if any) were satisfactory. I am eighteen years of age or older and freely and without reservation give my consent to serve as a subject in this study. By signing this form, I have not given up any of my legal rights as a research subject.

_____

Subject's Name Printed: First Middle Initial Last

_____

Subject's Signature Date

_____

Signature of Person Conducting Consent Discussion Date

SUBJECT SCREEN NO. _____
SUBJECT NO. _____

EXHIBIT B

SAMPLE CONSENT FORM

EXHIBIT C
SUBJECT INSTRUCTIONS - SURGICAL SCRUB

(July 17, 2003 - A ugust 15, 2003)

Today you will be given a kit of products (bar soap, shampoo, and deodorant/antiperspirant) to use exclusively during this study. Please set aside all products you normally use in these categories and use only the products in the kit. In addition, please refrain from using perfumes, deodorants or antiperspirants (other than the ones furnished), and anti-dandruff hair shampoos, do not swim in a chlorinated pool or hot tub and do not use tanning beds during the study.

Beginning today, no body lotions, medicated creams or ointments should be applied to any area of your skin. Also, do not take any antibiotics. These medications may affect the bacteria of the skin. If antibiotics are necessary due to illness, please report this to Hill Top Research.

Please use the rubber gloves provided with the product kit for all household chores involving detergents, acid, alkalis, and solvents until the completion of the study.

Please use the poly gloves provided with the product kit for pumping gas and when a disposable glove is desired.

If you have any questions regarding this study, please contact Glenna, at 513-831-3114 [redacted] between 8:00 a.m. - 5:00 p.m. or Ann Brady, Study Manager, after hours and on weekends at [redacted]

EXHIBIT C
SUBJECT BASELINE SCHEDULE

BASELINE 1

DATE: Friday, August 1, 2003

TIME of VISIT: 2:00 pm, 2:30pm, 3:00pm, 3:30pm

1. DO NOT BATHE, SHOWER OR WASH YOUR HANDS in the two hour period before the time of your visit to the lab. BE SURE THAT THE BAR SOAP IS THE LAST PRODUCT THAT YOU USE PRIOR TO VISITING THE LAB.

2. Please wear clothing that will allow easy access to your forearms.

3. Arrive about 15 minutes before your scheduled time.

4. You will be expected to have your fingernails clipped to a length not greater than 1/8 inch free-edge before reporting to the laboratory. If your nails are not clipped when you arrive, you must clip them at the laboratory.

5. You will be required to remove all rings, watches and bracelets before washing.

6. You will undergo a supervised handwash at the laboratory.

7. Approximate time at the laboratory - 1 hour.

BASELINE 2

DATE: Tuesday, August 5, 2003 **TIME:** SAME AS ABOVE

Follow the same instructions #1 - #7 as above in **BASELINE 1**.

BASELINE 3

DATE: Thursday, August 7, 2003 **TIME:** SAME AS ABOVE

Follow the same instructions #1 - #7 as above in **BASELINE 1**.

If you complete this phase of the study, you will be contacted on Friday, August 8 or Saturday, August 9, 2003 and told which test group you will be in. If you are eliminated, you will be called on Saturday, August 9, 2003.

EXHIBIT C
SUBJECT TEST SCHEDULE

Group No.	**I**	**II**	**III**	**IV**
Arrival time to lab for test days 1, 2, and 5(a.m.)				

TEST DAY 1

DATE: August 11, 2003

You will be at the lab for approximately 6.5 hours.

TEST DAY 2

DATE: August 12, 2003

You will be at the lab for approximately 8 hours.

Group No.	**I**	**II**	**III**	**IV**
Arrival time to lab for test days 3 and 4(a.m.)				

TEST DAYS 3 & 4

DATES: August 13 and 14, 2003

You will be at the lab for approximately 2.5 hours.

TEST DAY 5

DATE: August 15, 2003

You will be at the lab for approximately 6.5 hours.

If you have any questions regarding this study, please contact Glenna, at 513-831-3114[redacted] between 8:00 a.m. - 5:00 p.m. or Ann Brady, Study Manager, after hours and on weekends at [redacted]

EXHIBIT D
BASELINE BACTERIAL COUNTS

Subject Screen No.: _____ Subject Permanent No.: _____

Baseline 1 Sampling Date	Left Hand		Right Hand		
	10^{-4}	10^{-5}	10^{-4}	10^{-5}	
					_ Accept $\geq 1.5 \times 10^5$
					_ Reject $< 1.5 \times 10^5$
Date:	Ct./hand:		Ct./hand:		
	Ct./by:				Calc. By:
	Date:				Ck. By:

Baseline 2 Sampling Date	Left Hand		Right Hand		
	10^{-4}	10^{-5}	10^{-4}	10^{-5}	
					_ Accept $\geq 1.5 \times 10^5$
					_ Reject $< 1.5 \times 10^5$
Date:	Ct./hand:		Ct./hand:		
	Ct./by:				Calc. By:
	Date:				Ck. By:

Baseline 3 Sampling Date	Left Hand		Right Hand		
	10^{-4}	10^{-5}	10^{-4}	10^{-5}	
Date:	Ct./hand:		Ct./hand:		
	Ct./by:				Calc. By:
	Date:				Ck. By:

)MMENTS:_____
RAW DATA REVIEWED: _____
Underlined values used in calculations.
TNTC = Too numerous to count

EXHIBIT E
POST HANDWASH BACTERIAL COUNTS

Subject Permanent No.: _____

TEST DAY 1

Left Hand				
Time of Treatment: _____ am/pm				
Sampling Time: _____ am/pm				
1:75*	1:75*	1:750	1:7500	
Counted by: _____ / _____				
**Ct./Hand: _____				

Right Hand				
Time of Treatment: _____ am/pm				
Sampling Time: _____ am/pm				
1:75*	1:75*	1:750	1:7500	
Counted by: _____ / _____				
**Ct./Hand: _____				

Calculated By: _____ / _____
Calculations Checked By: _____ / _____

TEST DAY 2

Left Hand				
Time of Treatment: _____ am/pm				
Sampling Time: _____ am/pm				
1:75*	1:75*	1:750	1:7500	
Counted by: _____ / _____				
**Ct./Hand: _____				

Right Hand				
Time of Treatment: _____ am/pm				
Sampling Time: _____ am/pm				
1:75*	1:75*	1:750	1:7500	
Counted by: _____ / _____				
**Ct./Hand: _____				

Calculated By: _____ / _____
Calculations Checked By: _____ / _____

TEST DAY 5

Left Hand				
Time of Treatment: _____ am/pm				
Sampling Time: _____ am/pm				
1:75*	1:75*	1:750	1:7500	
Counted by: _____ / _____				
**Ct./Hand: _____				

Right Hand				
Time of Treatment: _____ am/pm				
Sampling Time: _____ am/pm				
1:75*	1:75*	1:750	1:7500	
Counted by: _____ / _____				
**Ct./Hand: _____				

Calculated By: _____ / _____
Calculations Checked By: _____ / _____
Data Reviewed By: _____ / _____
Underlined values used in calculations.
TNTC = Too numerous to count
*1:75 dilution is sum of three counts derived from counts derived from distributing 10 mL of 10^{-1} dilution of glove fluid over 3 plates
**Count/Hand = Bacterial count x 1/dilution factor.

Exhibit F-1

Subject Initials ______________ Subject #__________ HTR Study No.: 03-121432-106

Page No.:__________

ADVERSE EVENTS/CONCURRENT ILLNESSES

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date

Entry Date	Comment/Note:	Initials

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date

Entry Date	Comment/Note:	Initials

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-ship	Investigator Signature/Date

Entry Date	Comment/Note:	Initials

Note:Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity:	1=Mild	2=Moderate	3=Severe	
Relationship:	1=Definate	2=Probable	3=Possible	4=Unrelated
Action Taken:	1=None	2=Rx Therapy	3=Discontinued Study	4=Other (specify)
Outcome:	1=Resolved w/o sequelae	2=Resolved w/ sequelae (describe)	3=Ongoing	4=Death

[1]Serious Adverse Event/Experience
Revised February/2000

Exhibit F-2

Subject Initials _____ Subject #_____ HTR Study No.: 03-121432-106

Page No.: _____

ADVERSE EVENTS/CONCURRENT ILLNESSES

Symptom / Event	Onset Date	End Date	SAE[1] Y/N	Severity	Action Taken	Outcome	Relation-Ship	Investigator Signature/Date

Entry Date	Comment/Note:	Initials

Note:Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity:	1=Mild	2=Moderate	3=Severe	
Relationship:	1=Definate	2=Probable	3=Possible	4=Unrelated
Action Taken:	1=None	2=Rx Therapy	3=Discontinued Study	4=Other (specify)
Outcome:	1=Resolved w/o sequelae	2=Resolved w/ sequelae (describe)	3=Ongoing	4=Death

[1]Serious Adverse Event/Experience

Revised February/2000

August 7, 2003

HTR Study No.: 03-121432-106
STERIS REF.: 02-0002.00
Page:_____

PROTOCOL AMENDMENT #1

PROTOCOL FOR AN EVALUATION OF [redacted] AND A CHG SCRUB FOR ANTIMICROBIAL EFFECTIVENESS AND SUBSTANTIVITY IN THE SURGICAL SCRUB USING NORMAL SKIN FLORA

Reason for change: This amendment is needed to add an additional group of subjects to the neutralization assay. This assay was conducted one time and will be repeated to evaluate another neutralizer recipe. The neutralizer previously evaluated did not effectively neutralize the test products in the sampling solution.

A revised Consent Form-2 is attached reflecting the changes.

Approved for: **HILL TOP RESEARCH, INC.**

By:_____ 8-7-03
Gayle K. Mulberry, M.S. Date
Investigator

By:_____
IRB Date

Accepted by: **STERIS CORPORATION**

By:_____
Sponsor Representative Date

Study Title: "Protocol for an Evaluation of [redacted] and a CHG Scrub for Antimicrobial Effectiveness and Substantivity in the Surgical Scrub Using Normal Skin Flora"
Neutralizer Validation Study

CONSENT FORM-2 (Group 2)

INTRODUCTION: You are being asked to take part in a research study. Before you give your consent to be a subject, it is important that you take enough time to read and understand what your participation would involve. In preparing this consent form, it has been necessary to use some technical language. Please ask questions if there is anything you do not understand.

You will be given a signed copy of this consent form and any other necessary written information prior to the start of the study.

PURPOSE: The purpose of this research study is to assure that the materials used in the main study, for growing and counting bacteria recovered from the hands of subjects, will allow the growth of the bacteria. Approximately ten (10) people at least 18 years of age will be screened as potential subjects in this study. Six (6) subjects are expected to complete the one visit study.

TEST ARTICLES: You will be randomly assigned one of the two marketed surgical handwash products.

STUDY PROCEDURES: You must read and complete this consent form. As a participant, your hands and forearms will be washed with the assigned antibacterial surgical handwash product eleven times following specific directions. Your hands will be sampled after 1st, 2nd and 11th washes. Sampling is accomplished by having gloves placed on your hands. A mild soap-like solution will be added to the gloves. A laboratory technician will massage each gloved hand for one minute. Your hands will be removed from the gloves and the solution from each glove will be taken to the laboratory. The solution collected after the 1st and 2nd washes will be discarded. The solution collected after the 11th wash will be tested to determine if it can be neutralized to allow growth of bacteria, which the laboratory will add to it. Following the samplings, you will rinse your hands and forearms in tap water.

FEMALES OF CHILDBEARING POTENTIAL: You may not participate in this study if you are pregnant or nursing. As part of giving your consent you must agree to have a urine pregnancy test at the start of the study.

RISKS: Your hands and forearms may show a "reaction." A reaction could be redness, swelling, itching, cracking, peeling, or in rare cases, blistering.

No risks to you as a study participant, other than those described above as "reactions," are anticipated during the study. Reactions are usually due to irritation, although an allergic reaction might occur. If you become allergic, it is possible that future exposures to the same ingredient may cause a skin reaction. If this occurs, you will be provided with information to minimize the chance for future exposures.

You may experience risks or side effects that are not known at this time. You will be informed in a timely manner if new information becomes available that may influence your willingness to continue in this study.

BENEFITS: You will not benefit from the application of test products but the study results may allow a new or improved product to be marketed.

ALTERNATIVE PROCEDURES/TREATMENTS: Because you are not being treated for a medical condition, alternative treatments do not apply to this study.

CONFIDENTIALITY: Information concerning you that is obtained in connection with this study will be kept confidential by Hill Top Research, except that the sponsoring company whose product is being tested will receive a copy of the study records. The records will be coded to protect your identity. In addition, the Institutional Review Board (IRB) and government regulatory agencies, including the U.S. Food and Drug Administration (FDA), may inspect the records of the study. Information obtained in the study may be used for medical or scientific publication, but your identity will remain confidential.

MEDICAL TREATMENT: If in the course of this study you experience illness, discomfort or injury that appears to be a result of the study, Hill Top Research will provide you with medical care at no cost to you. Providing such medical care is not an admission of legal responsibility. If such illness, discomfort or injury does occur, ask any staff member to arrange a meeting for you with the appropriate personnel.

In certain cases of illness or injury resulting from this study, workers' compensation coverage may be available. In accordance with Ohio law, Hill Top Research has secured workers' compensation coverage for participants in its studies and tests, and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

WHO TO CONTACT: If you have any questions about this study or in case of an emergency, contact Glenna, Study Coordinator, at 513-831-3114 [redacted] during business hours (M-F, 8:00 A.M. - 5:00 P.M.) or Ann Brady, Study Manager, at [redacted] after hours. In addition, if you have any questions as to your rights as a research subject, contact the Institutional Review Board of Hill Top Research, Nancy J. Pelc, M.D., Chairman, at [redacted]

VOLUNTARY PARTICIPATION/WITHDRAWAL: Your participation in this research study is strictly voluntary. You may refuse to participate or may discontinue participation at any time during the study without penalty or loss of benefits to which you are otherwise entitled.

If you agree to participate in this study, you are also agreeing to provide Hill Top Research with accurate information and to follow study instructions as given to you. If you fail to follow the study instructions, your participation may be ended.

Your participation in the study may be discontinued at any time without your consent by the Investigator, the IRB, the FDA, or the sponsoring company.

COMPENSATION: You will be paid [redacted] for the completion of this study. You will be compensated according to the following schedule:

If you do not qualify	Visit 1	you will receive	[redacted]
If you complete	Visit 1	you will receive	[redacted]

Payment will be made at the end of the study.

There are no anticipated expenses to you for participating in this study. All test related materials will be provided at no cost to you.

CONSENT TO PARTICIPATE

I know that my participation in this study is voluntary and that I have the right to refuse to participate. I know that I may withdraw from the study at any time without penalty or loss of benefits to which I am otherwise entitled. If I withdraw or am dismissed for failure to obey rules or follow directions, I understand I will only be paid for the portion of the study that I have completed. If, in the judgment of the Investigator, it is best to discontinue my participation in the study for other reasons, I will be paid either in full or for that portion of the study already completed.

If I am a female of childbearing potential, I am not currently pregnant or nursing an infant. I am using an adequate means of birth control and, if I become pregnant or believe I have become pregnant, I will notify the Investigator immediately.

CONSENT: I have read all of the above information and have been given an opportunity to ask questions about this study. Answers to such questions (if any) were satisfactory. I am eighteen years of age or older and freely and without reservation give my consent to serve as a subject in this study. By signing this form, I have not given up any of my legal rights as a research subject.

_____

Subject's Name Printed: First Middle Initial Last

_____

Subject's Signature Date

_____

Signature of Person Conducting Consent Discussion Date

SUBJECT SCREEN NO. _____

SUBJECT NO. _____